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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,820	02/25/2005	Kai Fabian	MERCK-2979	9173
23599	7590	06/12/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			YOUNG, SHAWQUIA	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/525,820

Applicant(s)

FABIAN ET AL.

Examiner

Shawquia Young

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2-11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/25/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

Claims 1-14 are currently pending in the instant application.

### **I. *Priority***

The instant application is a 371 of PCT/EP03/08514, filed on August 1, 2003, which claims priority to GERMANY Application 102 40 026.1, filed on August 27, 2002.

### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on February 25, 2005 is impartial compliance with the provisions of 37 CFR 1.97 because of missing copies of references listed under the Foreign Patent Documents and the Non Patent Literature Documents sections. Accordingly, the information disclosure statement has been considered in part by the examiner.

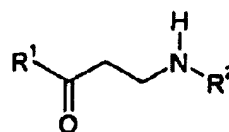
### **III. *Restriction/Election***

#### **A. *Election: Applicant's Response***

Applicants' election with traverse of Group II in the reply filed on May 12, 2006 is acknowledged. The traversal is on the ground(s) that: (1) the full scope of the claims have unity of invention and should not be subject to restriction; (2) the compounds of formula I are a "special technical feature" which defines a contribution over the art; and (3) the substituents for the formula do not vary extensively and do not result in vastly different compounds.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121 and 372. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that the full scope of the claims have unity of invention and should not be subject to restriction. Applicants discuss that all of the claims depend ultimately from claim 1 and all of the claims share the special technical feature of the base compound of formula I of claim I. However, the Examiner defines the special



technical feature of the compounds of formula I as but does not include the variables  $R^1$  and  $R^2$  in defining the special technical feature since these variables can be various substituents. As mentioned in the Office Action, the special technical feature is present in the prior art and therefore does not define a contribution over the prior art (See, Wilkerson, 4/948, 813 and Posselt, *et al.*, 3/658,845 for examples). The Applicants continue to argue this allegation is merely a conclusory statement and no proof is provided that the feature fails to define a contribution over the prior art. In the Office Action (on page 4), the Examiner cited the reference Wilkerson, 4/948, 813 as an example in which the special technical feature claimed by Applicants

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is known. In Posselt, *et al.*, examples 22, 23, and 25 (page 5, columns 9-10) also show that the special technical feature is already known in the prior art. These two references support the Examiner's argument that the compounds of formula I in claim 1 lack a special technical feature that defines a contribution over the prior art and thus results in a lack of unity of invention.

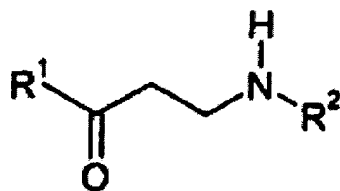
Applicants disagree that the substituents for the formula vary extensively and result in vastly different compounds. The Applicants argue that no evidence has been provided to meet the PTO's burden to show that this core structure does not define a constitution over the prior art. The Examiner points out that the R<sup>1</sup> variable is defined in claim 1 as a saturated, unsaturated or aromatic heterocyclic radical which in turn is more specifically defined in the specification on pages 4-5. The various heterocyclic R<sup>1</sup> groups listed in the specification do result in vastly different compounds. For example, R<sup>1</sup> could be defined as 2- or 3-thienyl; 1-, 2- or 3-pyrrolyl; 2-, 3-, or 4-pyridyl; or 2-, 4-, 5-, or 6-pyrimidinyl. The R<sup>1</sup> variable controls the classification for the compounds which means that each heterocycle in the above example are in different classes. Therefore different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The heterocycles listed on pages 4-5 of the specification belong to the following classes: 514, 544, 546, 548, and 549. However, each Class 514, 544, 546, 548 and 549 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety.

Subject matter not encompassed by elected Group II are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

***B. Status of the Claims***

i. Scope of the Elected Subject Matter

The scope of the subject matter is the compounds of formula (I) in claims 1, 12, and 13 wherein:



R<sup>1</sup> is 2- or 3-thienyl, which is unsubstituted or mono- or polysubstituted by R<sup>3</sup> and/or R<sup>4</sup> hydrogen;

R<sup>2</sup> is C<sub>1</sub>-C<sub>20</sub> alkyl;

R<sup>3</sup>, R<sup>4</sup> are independently H, alkyl, or C<sub>1</sub>-C<sub>20</sub> alkoxy, aryl, aryloxy or COOR<sup>2</sup>, F, Cl, Br, OH, CN, NO<sub>2</sub>, N(R<sup>2</sup>)<sub>2</sub> or NHCOR<sub>2</sub>;

ii. Extended Prior Art Search M.P.E.P. §803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended.

See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or

renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that the prior art search will not be extended unnecessarily to cover all non-elected species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, above, in response to the requirement to restrict the products of Formula (I), wherein: there was prior art of record (Ohkuma, *et al.*, 2000) that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **not extended or broadened** in pursuant to M.P.E.P. § 803.02.

#### IV. Rejections

##### **35 USC § 103 - OBVIOUSNESS REJECTION**

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 12, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ohkuma, et al.* (2000) and *Deeter, et al.* (1990). Applicants claim monoalkylaminoketones of the formula I defined in claim 1. The elected group is drawn to monoalkylaminoketones of the formula I, wherein R<sup>1</sup> is thienyl.

**The Scope and Content of the Prior Art (MPEP §2141.01)**

The primary reference, *Ohkuma, et al.* teaches general asymmetric hydrogenation of hetero-aromatic ketones including 3-(dimethylamino)-1-(thien-2-yl)-propan-1-one (*Ohkuma, et al.*, p. 1751, compound 13). The secondary reference *Deeter, et al.* teaches the asymmetric synthesis of LY248686 via reduction of 3-(dialkylamino)-1-aryl-1-propanones including 3-(dimethylamino)-1-(thien-2-yl)propan-1-one hydrochloride (page 7102, Scheme 1, compound 3).



**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art, *Ohkuma, et al.* and *Deeter, et al.* and the instant invention is that the applicants are claiming a secondary amine substituted with an alkyl group (i.e. methyl) on the alkylaminoethylene chain opposed to a tertiary amine disubstituted with two alkyl groups (i.e. methyl).

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

In *Ex parte Bluestone*, 135 U.S.P.Q. 199, it was established that the interchange of alkyl and hydrogen is obvious in and of itself. It was also established that secondary and tertiary amines are interchangeable. Interchanging a secondary and tertiary amine usually does not result in a significant difference in biological activities. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to substitute for instance, a hydrogen for a methyl on the tertiary amine of the alkylaminoethylene chain to form a secondary amine.

**V. Objections**

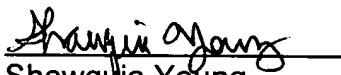
Claim 1 is objected to because of the following informalities: In the definition of variables  $R^3$  and  $R^4$ , the group  $NHCOR_2$  contains the variable R that is not present in the formula I structure and has not been properly defined. Appropriate correction is required.

## VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

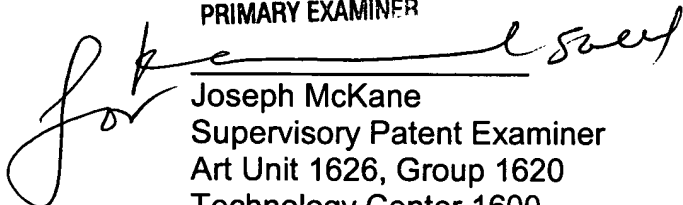
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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6/8/06

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